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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte
RICHARD WISNIEWSKI and LEONIDAS CARTWRIGHT LEONARD

Appeal 2007-3368
Application 10/057,610
Technology Center 3700

Decided: September 19, 2008

Before TONI R. SCHEINER, DEMETRA J. MILLS, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

SCHEINER, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims 1-5 and 20-29,[1] directed to a method of preserving a biopharmaceutical product. The claims stand rejected as obvious. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] Claims 6-19 are pending, but have been withdrawn from consideration.

DISCUSSION

The claimed invention is directed to a method of preserving a biopharmaceutical product by cooling and/or freezing the product in the interior cavity of a vessel that has an actively cooled interior wall, and an actively cooled heat exchange structure positioned coaxially with the central axis of the vessel. The heat exchange structure comprises an elongated pipe with one or more heat transfer members thermally coupled to it.

Claims 1, 3 and 25 are illustrative of the claimed subject matter:

1. A method of preserving a biopharmaceutical product comprising:
placing a medium comprising a biopharmaceutical product within a vessel having an interior cavity defined by an interior wall of said vessel, said vessel having a central axis;
flowing a cooling fluid through a removably mounted heat exchange structure within said interior cavity of said vessel, said structure comprising an elongated pipe having a central axis, wherein at least a portion of the central axis of said elongated pipe is positioned coaxially with the central axis of the vessel within said cavity, said structure having one or more heat transfer members thermally coupled thereto; and
actively cooling said interior wall using a fluid.

3. The method of claim 1, wherein said one or more of said heat transfer members are fins.

25. A method of processing a biopharmaceutical product comprising:
providing a vessel adapted to receive a medium comprising a biopharmaceutical product therein, said vessel having an interior cavity defined by an interior wall of said vessel and a heat exchange structure within said cavity, said heat exchange structure having an elongated pipe having a central axis, wherein at least a portion of the central axis of said elongated pipe is positioned coaxially with the central axis of the vessel within said cavity, said elongated pipe having one or more heat transfer members thermally coupled thereto;
placing a medium comprising a biopharmaceutical product within said vessel;

actively cooling said heat exchange structure by flowing a fluid through the elongated pipe; and

freezing the medium within said vessel to preserve said biopharmaceutical product.

Claims 1-5 and 20-29 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Wisniewski,[2] Kalhori,[3] and West.[4] [5]

Appellants have not argued the rejected claims separately. Therefore, we select claim 1 as representative of the claimed subject matter for the purpose of deciding this appeal, and claims 2-5 and 20-29 will stand or fall accordingly. 37 C.F.R. § 41.37(c)(1)(vii).

There is no dispute that Wisniewski discloses a method of preserving a biopharmaceutical product inside a freeze-thaw vessel by actively cooling both the interior wall of the vessel and a heat exchange structure located in the interior of the vessel, referred to by the Examiner as a "heat transfer coil pipe with fins" (Ans. 12), and described in the reference as a "one inch . . . seamless pipe with three 180 degree bends . . . [and] [h]eat transfer fins . . . welded to the external surface of the pipe" (Wisniewski, 134).

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[2] R. Wisniewski & V.L. Wu, *Large Scale Freezing and Thawing of Biopharmaceutical Drug Product*, Proceedings of the International Congress, Advanced Technologies for Manufacturing of Aseptic & Terminally Sterilized Pharmaceuticals & Biopharmaceuticals, Basel, Switzerland 132-139 (17-19 February 1992)

[3] B. Kalhori & S. Ramadhyani, *Studies on Heat Transfer From a Vertical Cylinder, With or Without Fins, Embedded in a Solid Phase Change Medium*, 107 Transactions of the ASME 44-51 (1985).

[4] U.S. Patent 2,114,642 to West, issued April 19, 1938.

[5] A rejection of the claims under 35 U.S.C. § 112, second paragraph, was withdrawn by the Examiner (Ans. 4).

Wisniewski's freeze-thaw vessel is shown in Figure 1, reproduced below:

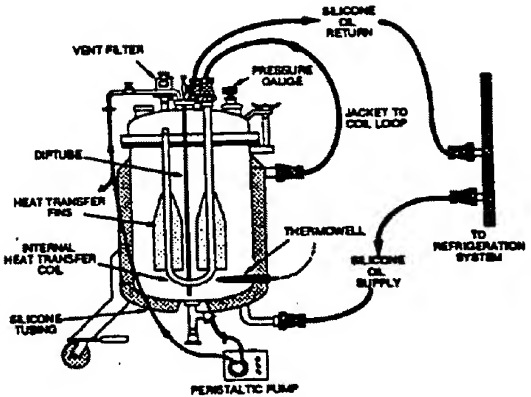

Figure 1 depicts the heat transfer coil in the interior of Wisniewski's freeze-thaw vessel.

The Examiner acknowledges that the heat exchange structure in Wisniewski's vessel is not "in the center" of the vessel (Ans. 15), that is, the heat exchange structure does not have a pipe with its central axis positioned coaxially with the central axis of the vessel. However, Appellants do not dispute the Examiner's factual determination that it was known in the art to use a heat exchange structure comprising an elongated pipe located along the central axis of a cylindrical freeze/thaw vessel, as evidenced by Kalhori's disclosure of a freeze/thaw vessel with a centrally located cylindrical "'spur-

tube' type heat exchanger with six heat transfer fins welded to it . . . almost identical to what applicants show in Figure 1 and 2 of the current application" (Ans. 21), and West's disclosure of "a central spur-tube heat exchanger used in combination with an external cooler" (Ans. 21). As noted by the Examiner, Kalhori teaches that cylinders with fins have "***superior heat transfer characteristics***" (Ans. 22; Kalhori 51, col. 2). We further note Kalhori's teaching that such heat exchangers provide "an economical and effective way of substantially enhancing the heat transfer rates" (Kalhori 51, col. 1).

Based on the combined teachings of the cited references, we agree with the Examiner that it would have been prima facie obvious for one of ordinary skill in the art to have used the known, centrally located "spur type" heat exchanger in Wisniewski's freeze/thaw vessel for preserving and/or freezing a biopharmaceutical product. The Examiner has articulated a reason for doing so, namely: to "improve heat transfer and to facilitate ease of construction as well as to facilitate easy removal from the frozen mass" (Ans. 22-23).

Appellants contend that Wisniewski "fails to teach or suggest appellants' claimed element of an elongated pipe positioned coaxially with a central axis of the vessel" (App. Br. 17), and there is no motivation to combine Kalhori's heat exchange structure with Wisniewski's vessel because "the devices disclosed in both articles involve different principles of freezing" (*id.* at 14). Specifically, Wisniewski "cools the container from the outside and the inside" but Kalhori "heats the container on the outside while cooling the container inside" (*id.*). Appellants further contend that there is

no "discussion or recognition of the problems associated with processing biopharmaceutical product" in Kalhori (App. Br. 14).

These arguments are not persuasive. Both Wisniewski and Kalhori are concerned with efficient cooling and/or freezing of a liquid medium using a heat exchange structure, and Kalhori teaches that a centrally located finned cylinder is an economical and effective heat exchange structure (Kalhori 51, col. 1). Appellants have not explained why one of ordinary skill in the art would have been dissuaded from using the known centrally located finned heat exchange structure taught by Kalhori (or West) in Wisniewski's freeze/thaw vessel. Nor have Appellants explained why one of ordinary skill in the art would not have considered Kalhori's heat exchange structure suitable for freezing biopharmaceutical products.[6]

Finally, we note that the present appeal is related to appeals in applications U.S. Serial No. 08/895,396 (Appeal No. 2007-0867) and U.S. Serial No. 09/881,909 (Appeal No. 2006-3326). Unlike the claims in those applications, the present claims do not require the formation of a thermal bridge between the internal wall of the vessel and the fins of the heat exchanger. Thus, the first and second declarations of Richard Wisniewski (dated January 23, 2002 and February 26, 2003, respectively), which address the formation of a thermal transfer bridge (or lack thereof) in the freeze-thaw

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[6] The declarations of Chris J. Burman (dated October 6, 1999), V. Bryan Lawlis (dated October 7, 1999), and David A. Vetterlein (dated October 6, 1999), submitted under 37 C.F.R. § 1.132, are concerned only with the meaning of the term "biopharmaceutical product," and do not address any problems associated with processing biopharmaceuticals.

device described in the Wisniewski reference, are not relevant to our decision in the present appeal.

CONCLUSION

The rejection of the claim 1 under 35 U.S.C. § 103(a) as unpatentable over Wisniewski, Kalhori, and West is affirmed, and claims 2-5 and 20-29 fall accordingly. 37 C.F.R. § 41.37(c)(1)(vii).

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv) (2006).

AFFIRMED

Ssc:

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